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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,071	09/25/2003	James R. Mault	MLFE.P003	4720

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EXAMINER	
NATNITHITHADHA, NAVIN	
ART UNIT	PAPER NUMBER
3735	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/672,071	MAULT ET AL.	
	Examiner	Art Unit	
	Navin Natnithithadha	3735	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 September 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 September 2007 has been entered.

Response to Amendment

2. Claims 1-5, 9-12, 17-18, and 25-33 have been amended. Claims 1-34 are pending.

3. The objections to Specification are WITHDRAWN in view of the Amendment.

Response to Arguments

4. Applicant's arguments, see Remarks, pp. 14-17, filed September 2007, with respect to claims 1-34 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

5. Claims 1-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1,12, 18, and 31, include the subject matter directed to "a system that is configured to alter a dietary regimen of the subject in an effort to reduce said deviation to within the defined amount in the event that the deviation is due to dietary causes, or to recommend a change in exercise regimen in the event that the deviation is due to excessive physical exertion". It is not clear as to whether this "system" is an element of the claimed "respiratory gas exchange monitor" because the "system" is not positively recited in the claims. Thus, no patentable weight will be given to the limitation "wherein the warning signal is monitored by a system that is configured to alter a dietary regimen of the subject in an effort to reduce said deviation to within the defined amount in the event that the deviation is due to dietary causes, or to recommend a change in exercise regimen in the event that the deviation is due to excessive physical exertion" because the "system" is not part of the claimed "respiratory gas exchange monitor".

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

6. Claim 32 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

As to claim 32, Applicant claims "[a] respiratory gas exchange monitor, said respiratory gas exchange monitor being configured to perform a method, comprising:..." The body of the claim recites step limitations directed to the method. Thus, the claim positively recites limitation that overlap statutory classes, i.e. apparatus and process. See MPEP 2173.05(p) II.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-8, 11-14, 17-20, 22-28, 31, 33, and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rummel et al, US 3,799,149 A ("Rummel"), in view of Harnoncourt et al, US 5,645,071 A ("Harnoncourt '071"), and further in view of Acorn et al, US 5,297,558 A ("Acorn").

Claims 1 and 2: Rummel teaches a respiratory gas exchange monitor ("an apparatus for the measurement of metabolic rate and breathing dynamics in which inhaled and exhaled breath are sense", including a computation circuit computing

"oxygen consumption, carbon dioxide production, minute volume and respiratory exchange ratio," see Abstract, see figs. 1 and 2) comprising:

a respiratory gas conduit ("mouthpiece") 16 configured to convey inhaled gases and exhaled gases of a subject (see col. 3, ll. 31-40);

a respiratory gas flow meter (combination of "inspiration spirometer" and "expiration spirometer") 12/20 coupled to said respiratory gas conduit 16, said respiratory gas flow meter 12-20 being configured to generate an output associated with both a volume of said inhaled gases ("INSP. VOL." Signal, see fig. 1) and a volume of said exhaled gases ("EXP. VOL.", see fig. 1);

a respiratory gas ("mass spectrometer") 28 coupled to said respiratory gas conduit, said respiratory gas sensor being configured to generate an output associated with a concentration of oxygen in said exhaled gases (mass spectrometer outputs "O2" signal, see fig. 1); and

a computation unit ("computer") 38/42/44/50 coupled to said respiratory gas flow meter 12/20 and said respiratory gas sensor 28 , said computation unit 42 being configured to process said output of said respiratory gas flow meter and said output of said respiratory gas sensor to determine an amount of carbon dioxide produced by said subject ("[t]he volume of carbon dioxide, CO2, produced for each respiratory cycle," see col. 8, l. 55, to col. 9, l. 2) and an amount of oxygen consumed by said subject ("the volume of oxygen consumed," see col. 8, ll. 36-53), said computation unit being configured to determine a respiratory quotient of said subject based on said amount of

carbon dioxide produced and said amount of oxygen consumed ("resultant quotient Y/Z," see col. 9, ll. 41-55).

Rummel does not explicitly teach a "*single* respiratory gas flow meter" (see claim 1) wherein "said respiratory gas flow meter is an ultrasonic flow meter" (see claim 2). However, Harnoncourt '071 teaches a computation unit (monitoring unit) II coupled to the "sensor head" I, wherein the "sensor head I" (see figs. 1 and 2), comprising: a respiratory gas conduit (not labeled, between "connectors" 6 and 7); a single respiratory gas flow meter ("continuous flow measuring device," see col. 4, ll. 35-37), which is a ultrasonic flow meter (ultrasonic receive elements, see col. 4, ll. 40-45) S2; a respiratory oxygen sensor (see col. 2, ll. 41-48, and col. 7, ll. 17-29). Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Rummel's inspiration and expiration spirometers 12/20 to ultrasonic transmit-receive elements S1/S2 taught by Harnoncourt '071 because Harnoncourt '071 explicitly discloses that the Harnoncourt '071 device is used "for the determination of physiologically relevant pulmonary function parameters" (see col. 4, ll. 36-40).

Rummel does not teach "wherein said computation unit includes a comparator function to compare said respiratory quotient to a reference respiratory quotient, said comparator function operable to trigger a warning signal in the event that it detects a deviation by a defined amount of said respiratory quotient to said reference respiratory quotient". However, Acorn teaches a computation unit ("microprocessor") 10 including a comparator function ("algorithm") to compare a respiratory quotient to a reference respiratory quotient (comparing "actual RER" to "0.90"), the comparator function

operable to trigger a warning signal ("error message") in the event that it detects a deviation by a defined amount of the respiratory quotient to the reference respiratory quotient (see col. 5, l. 46, to col. 6, l. 48). In addition, Acorn teaches that the computation unit monitors the warning signal to recommend a change in exercise regimen ("establishing the zone boundaries for the cardiovascular training zone", see col. 6, ll. 1-68). It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Rummel's "computer" 38/42/44/50 to include Acorn's "algorithm" that compares "actual RER" to "0.90" in order to "optimize either fat utilization or cardiovascular performance during an exercise regimen" (see Acorn, Abstract).

Claims 3 and 4: Rummel teaches the respiratory gas sensor 28 is an oxygen sensor (mass spectrometer outputs oxygen concentration), and the output of the respiratory gas sensor 28 is associated with a concentration of oxygen in inhaled gases (see col. 8, ll. 40-50).

Claims 5-8: Rummel teaches the computation unit 38/42/44/50 configured to process the outputs of the respiratory gas flow meter and the respiratory gas sensor to determine the concentration of oxygen in the exhaled gases (see col. 8, ll. 36-40), to determine the amount of carbon dioxide produced and the amount of oxygen consumed based on the inhaled volume, exhaled volume, exhaled oxygen concentration, inhaled oxygen concentration, and ambient oxygen concentration (see col. 8, l. 35, to col. 9, l. 2), and to determine the respiratory quotient based on a ratio ("resultant quotient Y/Z")

based on a ratio of the carbon dioxide produced and oxygen consumption (see col. 9, ll. 41-47).

Claim 11: Rummel teaches a display unit 46 coupled to the computation unit 38/42/44/50 (see fig. 1).

Claims 12, 13, 18, 19: Rummel in view of Harnoncourt '071 and Acorn teaches the claimed respiratory gas exchange monitor, comprising a single respiratory gas flow meter, a respiratory gas sensor, a computation unit, and a respiratory gas conduit, as discussed above in claims 1 and 5-8.

Claims 14, 17, 20, and 25: Rummel teaches the respiratory gas conduit 16 is a flow tube ("mouthpiece"), and a display unit 46 configured to provide indicia of the respiratory quotient ("CO2/O2 ratio", see col. 3, ll. 24-27).

Claims 22-24: Rummel teaches the computation unit 38/42/44/50 configured to determine a mass of carbon dioxide and oxygen in the exhaled gases based on the mass of the exhaled gases and a mass of nitrogen in the exhaled gases, to determine the mass of nitrogen in the exhaled gas based on a concentration of nitrogen in ambient air, and to determine a concentration of exhaled oxygen, amount of carbon dioxide produced, and amount of oxygen consumption (see col. 7, l. 53, to col. 8, l.10, and col. 8, l. 36, to col. 9, l. 2).

Claim 26: Rummel in view of Harnoncourt '071 and Acorn teaches the claimed respiratory gas exchange monitor, comprising a conduit, a first sensor, a second

sensor, and a computation unit, as discussed above in claim 1, with reference to a respiratory conduit, a single respiratory gas flow meter, a respiratory gas sensor, and a computation unit.

Claims 27 and 28: Rummel teaches the claimed flow tube and ultrasonic flow meter as discussed above in claims 14 and 2.

Claim 31: Rummel in view of Harnoncourt '071 and Acorn teaches the claimed respiratory gas exchange monitor, comprising integral sensor means for determining both a volume of inhaled gases of a subject, means for determining a concentration of oxygen in said exhaled gases, means for determining an amount of carbon dioxide produced and an amount of oxygen consumed, and means for determining a respiratory quotient, as discussed above in claim 1, with reference to a single respiratory gas flow meter, a respiratory gas sensor, and a computation unit.

Claim 33: Rummel in view of Harnoncourt '071 and Acorn teaches the claimed method of determining a respiratory quotient of a subject, as discussed above in claim 1, with reference to the respiratory gas exchange monitor, comprising a single respiratory gas flow meter, a respiratory gas sensor, and a computation unit.

Claim 34: Rummel teaches determining a mass of said exhaled gases (see col. 7, l. 53, to col. 8, l. 10), determining a mass of nitrogen in said exhaled gases (see col. 7, ll. 62-66), and determining said mass of carbon dioxide and oxygen in said exhaled gases

based on said mass of said exhaled gases and said mass of nitrogen in said exhaled gases (see col. 9, ll. 5-61).

8. Claims 15, 16, 21, and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rummel in view of Harnoncourt '071 and Acorn, as applied to claims 12, 18, and 26 above, and further in view of over Harnoncourt et al, US 5,503,151 A ("Harnoncourt '151").

Claims 15, 16, 21, and 29: Rummel in view of Harnoncourt '071 and Acorn does not teach the respiratory gas flow meter includes "a plurality of ultrasonic transducers" and the respiratory gas sensor, or second sensor, is "a fluorescence quench oxygen sensor." However, Harnoncourt '151 teaches a respiratory gas exchange monitor ("an apparatus for measuring the parameters of respiratory gases," see Abstract) 10, comprising: a plurality of ultrasonic transducers (ultrasonic sensor for measuring "respiratory volumetric flow rate," see col. 3, l. 37) 22; and a fluorescence quench oxygen sensor ("optical sensor," which uses "luminescence or fluorescence measurements [to determine] the oxygen concentration," see col. 2, ll. 3-16 and 46-57, col. 3, ll. 1-6, and col. 4, ll. 3-15) 28. Therefore, it would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Rummel in view of Harnoncourt '071 to include ultrasonic transducers and a fluorescent optical oxygen sensor because Harnoncourt '151 suggests that it is possible to determine respiratory volumes, respiratory frequency, oxygen uptake, release of CO2 and the concentration of anesthetic gases using the Harnoncourt '151 device (see col. 4, ll. 16-30), which are

the determined respiratory parameters of the Rummel device. In addition, Harnoncourt '151 discloses that an advantage to patented device is that it "renders possible a particularly compact design" (see col. 2, ll. 3-16).

9. Claims 9, 10, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rummel in view of Harnoncourt '071 and Acorn, as applied to claims 1 and 26 above, and further in view of Labuda et al, US 6,325,978 B1 ("Labuda").

Claims 9, 10, and 30: Rummel in view of Harnoncourt '071 and Acron does not teach the computation unit is configured to "compare said respiratory quotient with a reference respiratory quotient to determine a measure of deviation of said respiratory quotient with respect to said reference respiratory quotient" (claims 9 and 30), and to "determine said reference respiratory quotient based on a nutrient intake of said subject" (claim 10). However, Labuda teaches the following:

> A metabolic measurement (calorimetry) includes determination of a patient's energy requirements (in calories per day) and respiratory quotient (RQ). Interest in the measurement of caloric requirements has closely paralleled the development of nutritional support. For example, the ability to intravenously provide all the necessary nutrition to critically ill patients has only been accomplished within the last 25 years. Along with the realization that we need to feed patients, has come the need to know how much to feed them, what kind of nutrients (carbohydrates, lipids, protein) to feed them, and in what ratio the nutrients need to be supplied. The only true way to measure the caloric requirements of patients and to provide a non-invasive quality assessment of their response to nutrition is with indirect calorimetry. Airway O.sub.2 consumption and CO.sub.2 production can be measured non-invasively and provide a basis for the computations needed for a measurement of indirect calorimetry, a direct measurement of the metabolic status of the patient, and the patients' respiratory quotient...

> 5. When combined with a volume flow device (e.g. a pneumotach), VO.sub.2 (oxygen consumption) can be determined. Oxygen consumption is a very useful parameter in determining (a) oxygen uptake during ventilation or exercise, (b) respiratory exchange ratio or RQ (respiratory quotient) and (c) general patient metabolic status.

See col. 2, l. 54, to col. 3, l. 5, and col. 5, ll. 54-59. Thus, determining a patient's metabolic status, i.e. quality assessment of a patient's response to nutrition using indirect calorimetry, requires an assessment of the patient's caloric intake due to nutrition and the patient's respiratory quotient. It would have been obvious for one of ordinary skill in the art at the time the invention was made to modify Rummel's computation unit 38/42/44/50 to determining the patient's metabolic measurement, or calorimetry, based on the patient's energy requirement and respiratory quotient as defined by Labuda because this determination is within the scope of Rummel's objective of providing a system which "enables the accurate measurement of metabolic rates and breathing dynamics in varying environments and for subjects undergoing varying degrees of exertion" (see Rummel, col. 1, ll. 51-56).

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The other patents cited in the PTO-892 teach subject matter related to the Applicant's claims. The Examiner suggests reviewing these patents before responding to the present Office Action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Navin Natnithithadha whose telephone number is (571) 272-4732. The examiner can normally be reached on Monday-Friday, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II, can be reached on (571) 272-4730. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Navin Natnithithadha
Patent Examiner
Art Unit 3735
10/01/2007